# A Randomized Controlled Trial on Prophylactic Platelet Transfusion Prior to Central Venous Catheter Placement in Patients with Thrombocytopenia

Published: 20-01-2016
Last updated: 20-04-2024

Our objective is to determine in a controlled study whether not correcting thrombocytopenia prior to CVC placement is non-inferior compared to correcting. In the Netherlands annually 17.700 units PC are possibly unnecessary transfused, for the...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Platelet disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON50641

**Source**
ToetsingOnline

**Brief title**
PACER trial

### Condition

- Platelet disorders
- Procedural related injuries and complications NEC
- Haematological and lymphoid tissue therapeutic procedures

**Synonym**
Low platelet Count, Platelet deficiency

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Beurs ZonMW

## Intervention

**Keyword:** Central Venous Catheter, RCT, Thrombocytopenia, Transfusion

## Outcome measures

### Primary outcome

The primary outcome of this study will be a procedure-related relevant bleeding, occurring within 24 hours after the procedure. A WHO grade 2-4 up to 24 hours of randomization is defined as relevant bleeding. Based on observational studies we expect mainly grade 2 bleeding and no grade 3-4 bleeding. It should be noted that clinical relevance of a grade 2 bleeding is still relatively low. An assessment of bleeding will be standardized and performed by an independent research physician blinded to the transfusion strategy 1 and 24 hours after the procedure and when clinically indicated.

### Secondary outcome

- WHO grade 1 bleeding within 24 hours of CVC placement

- allergic transfusion reaction within 24 hours

- onset of acute lung injury within 48 hours.

- length of hospital stay

- number of RBCs and PC transfusions within 24 hours

- costs

Hemoglobin and platelet count will be measured at 1 and 24 hours after the procedure and when clinically indicated.

# Study description

### Background summary

Critically ill and hematologic patients undergoing therapy need a central venous catheter (CVC). These patients often suffer from thrombocytopenia at the moment of CVC placement. The current national and international guidelines support correction of thrombocytopenia up to a platelet count of 50 x 10^9/L prior to CVC placement. There is, however, no evidence to support correction of thrombocytopenia. On the other hand it has been proven that transfusion of platelet concentrates (PC) can be complicated by serious side effects. Furthermore, transfusion of PC is expensive (à ¤ 520,-). Retrospective studies suggest it is safe to place CVC independent of the platelet count down to 10 x 10^9/L.

### Study objective

Our objective is to determine in a controlled study whether not correcting thrombocytopenia prior to CVC placement is non-inferior compared to correcting. In the Netherlands annually 17.700 units PC are possibly unnecessary transfused, for the current study population the abandoning of PC transfusion prior CVC placement would result in a 9.2 million Euro cost reduction. HYPOTHESIS: Not correcting thrombocytopenia prior to CVC placement in patients is safe

### Study design

Multicenter randomized controlled trial

### Intervention

No transfusion (experimental arm) or transfusion (control arm) of 1 unit platelets concentrate (PC) prior placement of CVC

### Study burden and risks

CVC placement is suggested to be frequently complicated with bleeding as hematologic and critically ill patients often suffer from severe thrombocytopenia (5-75%) at the moment of CVC placement. However, this was based on placement of CVC using landmark techniques. From this perspective current national and international guidelines still support correction of thrombocytopenia up to a platelet count of 50x10^9/L prior to CVC placement.

Exposure of patients to blood products bears a risk for transfusion related morbidity and mortality.[8,9] Many years transfusion has been regarded as a

safe intervention; however during the past decades it has become clear that transfusion has a substantial risk for morbidity and mortality. Examples are transfusion-related acute lung injury, transfusion associated cardiac overload, allergic reactions, allo-immunization and the risk of transfusion related infections. Next to the burden of transfusion exposure, blood products are expensive and scarce.

In recent years CVC placement techniques have changed. It is now standard practice to perform ultrasound-guided placement which results in a lower number of puncture attempts and lower complication rate. As mentioned above prevention of bleeding complications is the reason to correct thrombocytopenia prior to CVC placement. Interestingly, recent retrospective studies suggest that the experience of the physician and the technique used (ultrasound vs. landmark) rather than the platelet count predicts bleeding complications. However, limitations of these studies were the small number of patients included and the absence of a control group. We believe that the improved standards of CVC placement, e.g. the use of ultrasound, make correction of thrombocytopenia prior to CVC placement obsolete.

# Contacts

**Public**
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
**Scientific**
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1. Age>18 years
2. Need for CVC placement at the clinician*s discretion
3. Platelet count between 10*50x109/L
4. INR*3.0
5. Informed consent

## Exclusion criteria

1. Use of therapeutic anticoagulant therapy, except single antiplatelet therapy
2. Contra-indication for PC transfusion, such Thrombotic thrombocytopenic purpura, or Congenital IgA deficiency.
3. Randomization in the current trial, in the previous 24 hours.
4. Patients with a history of congenital or acquired coagulation factor deficiency or bleeding diathesis.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL
Recruitment status: Recruitment stopped

| | |
|---|---|
| Start date (anticipated): | 23-02-2016 |
| Enrollment: | 392 |
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 20-01-2016 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 24-02-2016 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 26-02-2016 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 03-10-2016 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 25-11-2016 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 15-01-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 19-11-2018 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 22-05-2020 |

| | |
|---|---|
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL54569.018.15 |